K082054

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510(k) Summary of Safety and Effectiveness
Gyrus ACMI, Inc.
Gyrus ACMI Y-Connector

General Information

Manufacturer:	Gyrus Medical Ltd. Fortran Road, St. Mellons Cardiff, United Kingdom
Establishment Registration Number:	9617070
Submitter:	Gyrus ACMI, Inc. 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	3003790304
Contact Person:	Terrence E. Sullivan Vice President, Regulatory Affairs
Date Prepared:	July 18, 2008

Device Description

Classification Name:	Electrosurgical Cutting & Coagulation Device and Accessories (21 CFR 878.4400), Class II General & Plastic Surgery Panel
Trade Name:	Gyrus ACMI PK (PlasmaKinetic) SuperPulse System
Generic/Common Name:	Electrosurgical Generator and Accessories

Predicate Device

Gyrus PlasmaKinetic SuperPulse System Generator and Accessories	K031085

K082054

Intended Uses

The Gyrus ACMI PK (PlasmaKinetic) SuperPulse System is intended for use for the ablation, removal, resection, and coagulation of soft tissue, and where associated hemostasis is required in open, endoscopic, and laparoscopic surgical procedures.

These devices are marketed as reusable devices; methods for cleaning, disinfecting and sterilization are included in latter sections of this submission under Section 12.0, "Cleaning".

Product Description

The currently marketed Gyrus ACMI PK SuperPulse System is a bipolar RF generator that accepts a variety of disposable hand pieces that utilize a PlasmaKinetic (PK) waveform. The generator face includes two sockets that allow a range of hand pieces to be utilized in a dry field environment, although only one socket may be active at any given time.

The Gyrus ACMI PK SuperPulse System General Purpose Electrosurgical Generator employs a system of automatic instrument detection, through a capacitor located in the hand piece connector plug. This ensures that only the allowable range of waveform output and power level can only be applied to the instrument irrespective of the output socket. Accessories presently provided with the Gyrus ACMI PK SuperPulse System include a power cable and a foot switch. It should be noted that this footswitch is also used with the Gyrus ACMI General Surgery Workstation generator (cleared under K050550).

This Special 510(k) proposes the addition of a new optional accessory, the Dual Footswitch Connector Cable. The Dual Footswitch Connector Cable allows for easier use of the Gyrus ACMI PK SuperPulse System when multiple surgeons are present. This is achieved by allowing the connection and use of two footswitches on the same generator. The indications for use, principles of operation, energy waveform outputs, and accessories of the Gyrus ACMI PK SuperPulse System with the Dual Footswitch Connector Cable accessory remain the same as the currently marketed Gyrus ACMI PK SuperPulse System.

Summary of Safety and Effectiveness

The proposed modifications for the Gyrus ACMI PK SuperPulse System, as described in this submission, are substantially equivalent to the predicate device. The proposed addition of the Dual Footswitch Connector Cable as an accessory is not a substantial change or modification, and do not significantly affect the safety or efficacy of the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Gyrus ACMI, Inc.
% Mr. Terrence E. Sullivan
VP, Regulatory Affairs
136 Turnpike Road
Southborough, Massachusetts, 01772

AUG - 6 2008

Re: K082054
Trade/Device Name: Gyrus ACMI PK SuperPulse System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 18, 2008
Received: July 21, 2008

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Gyrus ACMI PK SuperPulse System

510(k) Number: K082054

Intended use:

The Gyrus ACMI PlasmaKinetic SuperPulse System is intended for use for the ablation, removal, resection, and coagulation of soft tissue, and where associated hemostasis is required in open, endoscopic, and laparoscopic surgical procedures.

The device is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: __ X __ **OR** Over-the-Counter Use: _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K082054